THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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| ***In re*: VALSARTAN, LOSARTAN, and IRBESARTAN PRODUCTS LIABILITY LITIGATION** | Master Docket No. 19-2875 (RBK/SAK) |
| | **Opinion on Liability Expert Reports under *FRE* 702** |
| *This Document Applies to All Actions* | |

**KUGLER,** United States District Judge:

**BEFORE THE COURT** in this multidistrict litigation ("MDL") are several motions from both parties seeking to preclude reports of the other party's liability experts. Tables 1 and 2 list the parties' motions to preclude, which this Opinion and an accompanying Order of this date resolve;

**The COURT HAVING REVIEWED** the parties' submissions without a hearing in accordance with *Loc.R. 78.1 (b)*, for the reasons stated below, and for good cause shown,

**IT IS HEREBY ORDERED:**

Plaintiffs' motion Doc. No. 2286 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Ali Afnan's liability opinions;

Plaintiffs' motion Doc. No. 2297 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Timothy Anderson's liability opinions;

Plaintiff's motion Doc. No. 2289 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Steven Baertschi's liability opinions;

Plaintiffs' motion Doc. No. 2293 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Michael Bottorff's liability opinions;

Plaintiffs' motion Doc. No. 2298 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for John Flack's liability opinions;

Plaintiffs' motion Doc. No. 2299 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Timothy Kosty's liability opinions;

Plaintiffs' motion Doc. No. 2301 is **GRANTED IN PART AND DENIED IN PART** as specifically

stated below for Akhilesh Nagaich's liability opinions;

Plaintiffs' motion Doc. No. 2295 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Roger Williams' liability opinions;

Plaintiffs' motion Doc. No. 2288 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Fengtian Xue's liability opinions;

Defendants' motion Doc. No. 2284 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Susan Bain's liability opinions;

Defendants' motion Doc. No. 2287 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Laura Craft's liability opinions;

Defendants' motion Doc. No. 2292 is **DENIED** as to the liability opinions of Steven Hecht;

Defendants' motion Doc. No. 2292 is **GRANTED IN PART and DENIED IN PART** as specifically stated below for Ramin Najafi's liability opinions;

Defendants' motion Doc. No. 2291 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Kaliope Panagos' liability opinions.

Defendants' motion Doc. No. 2285 is **GRANTED IN PART AND DENIED IN PART** as specifically stated below for Laura Plunkett's liability opinions.

Defendants' motion Doc. No. 2296 is **DENIED** as to the liability opinions of Philip Russ.

## 1.0 BACKGROUND

The Valsartan MDL arose from an extensive Food and Drug Administration ["FDA"] recall in the U.S. of generic hypertensive, prescription drugs ["Valsartan" or "Valsartan-containing drugs" or "VCDs"]. To be clear, as used herein, the term "VCD" refers to valsartan-containing drugs that were contaminated with probable genotoxic human carcinogens in the form of nitrosamines, N-nitrosodimethylamine ("NDMA") and N- N-nitrosodiethylamine ("NDEA").

Beginning in July 2018 and upon the FDA's discovery that VCDs sold in the U.S. were contaminated with these nitrosamines, the FDA continued to recall VCDs into 2021. The recalls concerned VCDs manufactured and/or finished into pills by several defendants not headquartered in the U.S., including: in China: Zhejiang Huahai Pharmaceuticals Ltd.["ZHP"]; in India: Mylan Pharmaceuticals Ltd. ["Mylan"]; Aurobindo Pharmaceuticals Ltd.["Aurobindo"]; Hetero Pharmaceuticals Ltd. ["Hetero"]; and Torrent Pharmaceuticals Ltd. ["Torrent"]; and in Israel: Teva Pharmaceuticals ["Teva"]. Most of the foreign drug manufacturers also have U.S. subsidiaries that either put the drugs into finished form and/or distributed them in the U.S.

The Court has certified three classes of plaintiffs: a Personal Injury class, an Economic Loss

class, and a Medical Monitoring Class. These motions to preclude relate to the possible liability of defendants for the formation of nitrosamines in their Active Pharmaceutical Ingredient ["API'] during its manufacture and for including the nitrosamine-contaminated API into finished drug products. The liability reports are especially appropriate because a bellwether trial of the Third Party Payor segment of the Economic Loss class has been scheduled for 2024.

As the parties know well the background and procedural history of the MDL, the Court foregoes an exposition and recommends a review of Doc Nos. 675, 728, 775, 818, 839, 1019, 1753, 1811, 1825, 1838, 1958, 1974,1994, 2261, 2368, 2343, 2518, 2529, 2535, 2546, and 2555, as needed.

## 2.0 LEGAL STANDARD: RULE 702 and DAUBERT V. MERRELL DOW PHARMACEUTICALS, INC., 509 U.S. 579 (1993)

*Federal Rule of Evidence ("FRE"* or "*Rule"*) *702* governs admission of expert testimony in federal court. The Supreme Court charged the district courts with a gatekeeping "function over such testimony to ensure it has a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590-591 (1993)

The Third Circuit has acknowledged that relevance and reliability are requisite qualities of expert testimony, with the former evaluated under the standard expressed in *Rule 401*. *U.S. v. Ford*, 481 F.3d 215, 218 (3d Cir. 2007). As for relevance or fit, expert testimony must have a tendency to make the existence of any fact of consequence to the determination of the task at hand more probable or less probable than it would be without the evidence. *Ibid. citing Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002).

As for reliability, that expert testimony admitted at trial is or has:

(a) scientific, technical, or other specialized knowledge that will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) a basis on sufficient facts or data;

(c) been deduced from reliable principles and methods; and

(d) a reliable application of the principles and methods to the facts of the case. *Rule 702.*

Besides these, a court may consider the following factors enumerated in *Daubert,* which relate to the expert's methodology in arriving at the opinion*:*

(1) whether the methodology or theory has been or can be tested;

(2) whether the methodology or theory has been subjected to peer review and publication;

(3) the methodology's error rate and the existence and maintenance of standards controlling the technique's operation; and

(4) whether the methodology or technique has gained general acceptance in the relevant scientific community. *Daubert*, 509 U.S. at 593-94.

While "Rule 702 sets forth specific criteria for the court's consideration, the *Daubert* inquiry is fluid and will necessarily vary from case to case" (*Amorgianos*, 303 F.3d at 266 quoting *Daubert*, 509 U.S. at 593) and do not form a definitive test. Proffered expert testimony can fail all four of the *Daubert* methodology factors and still be admitted so long as the court takes a hard look at the expert's methodology. This means "*any* step that renders the expert's analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology. In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir.1994). [emphasis in the original].

A court has "considerable leeway in deciding [ ] how to go about determining whether particular expert testimony is reliable" (*Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152, (1999)). "The evidentiary requirement of reliability is lower than the merits standard of correctness" and a judge may not and need not think an expert is correct. *Paoli*, 35 F.3d at 744–45. That is, admissibility of an expert's opinion depends not on "[w]hether the ... expert might have done a better job" (*Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 809 (3d Cir. 1997)), but is a multi-factor assessment of the testimony's fit and reliability.

Ultimately, a court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152. Emphasizing that a court's inquiry under *Rule 702* must focus "solely on principles and methodology, not on the conclusions they generate" (*Daubert*, 509 U.S.at 595), the Supreme Court later clarified that "conclusions and methodology are not entirely distinct from one another." *General Electric Company v. Joiner,* 522 U.S. 136, 146 (1997). Even though "[t]rained experts commonly extrapolate from existing data, nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered" (*Ibid.)* and preclude the testimony.

And, it is only after the court's decision on the admissibility of the expert's opinion that questions of its credibility arise. However, whether the expert's testimony is credible—carries weight or is correct—is not resolved by the court in deciding a motion to preclude, but is for the fact-finder to determine. *Kannankeril* , 128 F.3d at 810.

## 3.0 MOTIONS THIS OPINION RESOLVES

Table 1 lists in alphabetical order the defendants' liability experts and Table 2 the plaintiff's

liability experts. These tables also list the ECF Doc. No. of the opposing party's motion to preclude. Each liability report was opposed by the other part, unredacted, and filed under sea. The Court review the unredacted reports. Redacted reports are available for purview on ECF.

**Table 1: Defendants' Liability Experts**

| Expert | ECF Doc No. of Plaintiffs' Motion to Preclude | Retained by Which Defendant | Report Date |
|---|---|---|---|
| Ali Afnan, PhD | 2286 | ZHP | Amended Report 11 Jan 2023 |
| Timothy Anderson, MS, MBA | 2297 | Teva | 12 Jan 2022 |
| Steven Baertschi, PhD | 2289 | Teva & ZHP | 19 Dec 2022 |
| Michael Bottorff, PharmD | 2293 | Defendants | 12 Jan 2022 |
| John Flack, MD, MPH | 2298 | Defendants | 19 Dec 2022 |
| Timothy Kosty, RPh, MBA | 2299 | Defendants | 19 Dec 2022 |
| Akhilish Nagaich, PhD | 2301 | Torrent | 22 Dec 2022 |
| Roger Williams, MD | 2295 | Teva | Revised Report 28 Jan 2023 |
| Fengtian Xue, PhD | 2288 | ZHP | 22 Dec 2022 |

**Table 2: Plaintiffs' Liability Experts**

| Expert | ECF Doc No. of Defendants' Motions to Preclude | Retained by | Report Date |
|---|---|---|---|
| Susan Bain, DRsc | 2284 | Plaintiffs | 31 Oct 2022 |
| Laura Craft, MPH, JD | 2287 | " | 31 Oct 2022 |
| Stephen Hecht, PhD & Ramin Najafi, PhD | 2292 | " | 6 Jul 2021<br>31 Oct 2022 |
| Kaliope Panagos, PharmD | 2291 | " | 31 Oct 2022 |
| Laura Plunkett, PhD | 2285 | " | 31 Oct 2022 |
| Philip Russ, BS | 2296 | " | 31 Oct 2022 |

## 4.0 DEFENDANTS' LIABILITY EXPERTS

### Ali Afnan, PhD

Plaintiffs' motion Doc. No. 2286 is **GRANTED IN PART AND DENIED IN PART.** Defendants asked Afnan to evaluate and respond to plaintiffs' experts who averred that, in its manufacture of the valsartan API, defendant Zhejiang Huahai Pharmaceuticals Co. Ltd. ["ZHP"] was not in compliance with

FDA requirements, including current Good Manufacturing Processes ["cGMPs"].

Afnan's general opinion is that, in making and selling valsartan API, ZHP complied not only with FDA guidances setting forth cGMPs but also with standards established by the U.S. Pharmacopeia ["USP"] and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH"). Afnan's opinion boils down to: ZHP is not liable for the introduction of nitrosamines into its API because it practiced the industry standards of the time in testing the purity and quality of its API. An underlying premise of his opinion is that, since the FDA did not know how to adequately test for nitrosamines before its 2018 recall of VCDs, how could a valsartan API drug manufacturer be expected to know how to do that.

The Court views this "industry standard" premise (which is repeated in similar ways in many opinions reviewed here) as bordering on a legal opinion as to the responsibility of the API and finished dose manufacturers. The Court clarifies that such opinion is to be presented to a fact finder in decidedly limited way. That is, Afnan (and other experts) may testify about a "fact" that arises from their chemical, medical, toxicological, regulatory, etc. expertise: e.g., that to the best of their knowledge and experience, at the time of the FDA recall of VCDs in 2018, the FDA had not yet developed an adequate test for nitrosamines formed in ZHP's solvent extraction processes.

Importantly, Afnan (and other experts) may NOT testify, imply, hint, or suggest to a fact-finder as to the LEGAL MEANING, i.e., the liability meaning, of the lack of such guidance, and specifically that the FDA's lack of guidance gives defendants a pass on liability. Such opinion is not helpful to the fact finder, contrary to *Rule 702(a).*

Specifically, Afnan is **PRECLUDED** from presenting to a fact finder the opinions in the paragraphs listed below because they cross over into legal opinions for which he is unqualified to assert:

In ¶24 of his report, that the VCDs were not adulterated because the way he asserts this opinion is not based on an FDA's or other legal body's determination;

In ¶53, that the lack of standards or guidance in any industry-recognized standard such as an FDA guidance, USP standard, etc. for testing nitrosamines provides **LEGAL** assurance that ZHP was diligent in testing for nitrosamines; and that the specific guidance document in this paragraph does not provide legally enforceable requirements for pharmaceutical product manufacturers;

¶64, because it is pure *ipse dixit*;

¶69, any assertion of therapeutical equivalence between VCDs and the RLD, Diovan®;

¶138, as this paragraph states Afnan's opinions about the definitions of "adulterated" and "bioequivalent", which Afnan is not qualified to state and is therefore not helpful to the fact-finder.

¶153, because Afnan is no legal expert who may opine on the meaning and implications of the

causation opinion of 6 Dec 2022 in *In re Zantac* MDL.[1]

The opinions in other paragraphs of Afnan's report are **NOT PRECLUDED**.

**Timothy Anderson, MS, MBA**

Plaintiffs' motion Doc. No. 2297 is **GRANTED IN PART AND DENIED IN PART**. Teva asked Anderson to opine on documents discussing Teva's compliance with cGMPs based on inspection reports by the FDA and the Government of Malta Medicines Authority of Teva manufacturing facilities. Teva also asked Anderson to review Teva's periodic audits of reports from ZHP and Mylan (Teva's API suppliers). Anderson's task was to detect whether Teva audits of its suppliers' and regulators' reports revealed any suspicions about API contamination. Put differently, Anderson is looking at Teva's own reviews of external reports to see if Teva could or should have known the API was contaminated. Lastly, Teva asked him to opine on the assertions of plaintiff's liability expert John Quick regarding Teva's lack of compliance with FDA guidances and regulations.

Anderson's general opinion is that he saw nothing in Teva's own audits of the periodic reports from regulators or API supplies to suggest that nitrosamines were, would be, or could be present in API purchased from ZHP and Mylan. Moreover, Anderson's report lacked a statement of reliable methodology. The Court has interpreted his methodology from the content of his report:

- basically he compares Teva's internal reviews (audits) of external reports against what is stated in the external reports from the API manufacturers and the regulatory authorities;

-to contextualize his "review" of Teva's "reviews", he reads and interprets the relevant FDA and Malta cGMPs contemporaneous to the VCD contamination; and

-he reads and interprets Teva's Quality Control ["QC"] and Risk Management policies and Standards of Procedures ["SOP]".

To form his opinions, Anderson compares his interpretations of the cGMPs with his interpretation of Teva's QC and Risk Management procedures. He opines Teva acted in line with contemporaneous cGMPs and acted diligently with regard to testing for nitrosamines in the API it received from ZHP and Mylan.

Anderson's opinions rely on his self-identification as an "Expert Reader" of cGMPs, which creates the methodological problem of self-reference. Identifying oneself as an expert and then opining from the position of "self-defined expert" lacks reliability as it is based only on expert's declaration that he is an expert.

As alluded to above, his report lacks a transparent explanation of his methodology. At its most

[1] Which by the way Afnan is incorrect about.

fundamental, Anderson compared what Teva reported it saw (in its audits) with the periodic reports from the regulators and API manufacturers. He then opined that Teva's audits did not disagree with these reports. Anderson also opined that Teva's audits did not disagree with his interpretations of the regulators' cGMPs. In essence, Anderson's opinions are based solely on his interpretations of the alignment between Teva's audits and the regulators' cGMPs. His opinion represents no independent methodology against which his opinion can be measured.

A third problem in Anderson's report is that he opines that Teva was complying with "industry standards" set forth by regulatory authorities. In fact, he opines that Teva adopted the industry standard of NOT independently verifying the information in API suppliers' reports. As pointed out earlier, compliance with "industry standards" constitutes a legal opinion as to negligent or diligent conduct, a conclusion Anderson is not qualified to make and which is not helpful to the fact-finder. To be clear, Anderson's unstated bridging argument is that compliance with "industry standards" cannot ever fall short of the diligence needed to demonstrate the requisite duty of care. Not only is this argument circular but it sets up a house-of-cards "legal" standard for the duty of care. Put simply, compliance with industry standards does not automatically impart compliance with the legal "duty of care". Equating "industry standards" to the legal "duty of care" must rely on more than an expert's mere assertions. Indeed, who determines if the legal "duty of care" has been met is for the fact-finder, not an expert, to determine.

In addition, Anderson never specifies whether he has looked at a sample or all of Teva audits of the regulators' or suppliers'. Again, this points to a lack of reliable methodology. Anderson has set up no independent yardstick of factors, criteria, checkpoints that would provide even an ordinal analysis as to the reliability of his review of Teva's "reviews" of ZHP reports. Simply, there is a complete absence of an underlying recognized rationale or literature search or scientific method supporting Anderson's opinion that Teva's "reviews" sufficed.

The opinions, implications, and statements in the following paragraphs and sections in Anderson's report are **PRECLUDED**:

In ¶¶ 22-25 there is cited no reliable methodology to back up his opinion that Teva did not have evidence from regulatory auditors and inspectors that nitrosamines would be present in the API Teva got from ZHP or Mylan;

In ¶28 he states a legal opinion about the meaning of an FDA Guidance;

In ¶¶77, 80, 81, 90, 181 he implies he is an expert on the meaning and interpretation of FDA regulations and on the FDA definition of adulteration and on how the FDA applies that definition to drugs that contain contaminants not included in the Orange Book formulation;

In the Appendix Attached to Anderson's Report: All Information in Tables on pages 36 to 38;

Anderson's Self-Identification as an "Expert Reader" of Health Regulator's cGMPs, Guidances, etc. because that term is undefined and therefore constitutes *ipse dixit*;

As the precluded liability opinions are intertwined throughout Anderson's report, **ONLY** the opinions in the following paragraphs of Anderson's report are **NOT PRECLUDED**: ¶¶30 - 43.

**Steven Baertschi, PhD**

Plaintiff's motion to preclude Doc. No. 2289 is **GRANTED IN PART AND DENIED IN PART**. Baertschi's report has the same overall thesis as Anderson's and Afnan's: As there was no industry standard, i.e., guidance or cGMP from the FDA or elsewhere, to recommend or identify a test for nitrosamines when ZHP solvent extraction changes were introduced, Teva was not negligent for not testing for nitrosamines using certain Gas Chromatographic methods. Put simply, following industry standards at the time relieves Teva from negligent liability for the introduction of nitrosamines in its VCD finished dose products sold in the U.S.

Baertschi's methodology is not clearly reliable because he reviewed only those documents that support his opinion summary stated in the previous paragraph. He did not review the cGMPs and all the relevant FDA reports, warning letters, etc. relating to the Valsartan recalls of the Teva's products and ZHP's API.

In his opinion summary in ¶¶12-16, Baertschi states that analyzing low-level nitrosamine impurities in VCDs is extremely difficult and calls for specialized equipment, analytical testing methods and expertise. Further, prior to the FDA recall of VCDs in July 2018, industry standards for specification testing of VCDs did not include methods capable of detecting nitrosamines at the levels at issue in the MDL. Moreover, Teva acted as a reasonably prudent and careful manufacturer in making valsartan finished dose from the ZHP API manufactured by the changed solvent processes because it used the testing required by the USP Monography, the ANDA, and ICH M7 and conducted appropriate reviews and testing of residual solvents.

Baertschi opines it was reasonable and appropriate for Teva not to perform further analysis of unidentified peaks seen on Teva's chromatograms of valsartan API batches, precisely because the collective industry "mindset" had not indicated that such difficult testing was necessary. Thus, Baertschi's opinion relies on his interpretation that, when ZHP solvent extraction changes occurred, the "industry culture" either did not know or did not recognize the possibility of nitrosamine contamination resulting from those solvent changes. Therefore Teva not only gets a pass on negligence liability but, because of this lack of knowledge, Teva's valsartan finished doses must be considered the same as the RLD.

Baertschi's opinion about what the industry knew, i.e., the industry "culture" at the time of ZHP

solvent extraction process changes, is not backed up by reliable methodology, that is, a positivistic, reliable search either in the literature or by random sampling of industry experts' opinions. Baertschi's opinion, like the previous ones reviewed here, is based on reference to what the Court has been calling "industry standards", such as FDA guidances, USP monographs, etc. It presumes that the absence of such industry standards suffices to relieve negligence liability.

Baertschi's opinions suffer from the same, unstated bridging argument that lack of knowledge, and reliance on that, relieves liability. This "I didn't know and likely couldn't have known" argument tries to give the fact-finder an *a priori,* wrapped-up legal standard as to the legally appropriate duty of care, which Baertschi is not qualified to do.

The opinions in the following paragraphs and sections in Baertschi's report are **PRECLUDED:**

¶¶14 – 16 all opinions here, especially that Teva's valsartan finished dose product are the "same" as the RLD, are not supported by reliable methodology, such as FDA literature, etc.

¶¶29 – 32 all opinions here, and especially, that drug manufacturers do not test for every impurity and it is particularly difficult to detect and quantify impurities at such low levels as nitrosamine levels found in valsartan because they are not supported by reliable methodology;

¶¶ 33 - 37 all opinions here, and especially, that the specification testing for VCDs prior to July 2018 did not include testing capable of detecting NDMA at the levels at issue and that Teva's finished dose product was the "same" as the RLD, because they are not supported by reliable methodology.

¶¶38 - 56 all opinions here, and especially, that Teva's following industry standards sufficed to show it acted as a reasonably prudent and careful actor, because that is not supported by reliable methodology and is not helpful to the fact-finder. What this means is that all his opinions regarding Teva's prudent conduct is pure *ipse dixit*.

¶¶58 – 61 all opinions here, for the same reasons as for ¶¶38 – 56.

**Michael Bottorff, PharmD**

Plaintiffs' motion Doc. No. 2293 is **GRANTED IN PART AND DENIED IN PART.** Bottorff's liability report is the very same as his class certification one, which raises a question as to its lack of fit or relevance to the task at hand.

To keep this simple, the Court both reiterates its findings in its Class Certification Opinion and then addresses the precluded information in Bottorff's report regarding liability:

As expected, the following of Dr. Bottorff's statements in his Class Certification Report are **PRECLUDED** from being presented to a fact finder as these improperly expanded on his causation opinion:

- "Oral doses at the levels detected in the generic valsartan at issue in this litigation are metabolized in the liver almost completely, **preventing** exposure to other tissues and organs" (Bottorff Class Certification Report at 48:761-762);

- "NDMA/NDEA in valsartan **will not reach systemic circulation**" (Bottorff Class Certification Report at 47: 779); and

- "DNA repair mechanisms in humans can be as much as 10 times higher than that in rats, indicating a more active DNA repair in humans compared to rats" (Bottorff Class Cert. Report at 52:830-831).

Moreover, **almost all** opinions in Bottorff's class certification report is **PRECLUDED** from being presented to a fact finder as unfit for purpose of pointing out liability from a pharmacological perspective.

What is **NOT PRECLUDED** in Bottorff's liability report is the simple statement that contaminated VCDs function the same in the human body as uncontaminated VCDs. Although Bottorff's report offered no pharmacological evidence or reliable test results to support this statement, plaintiffs may seek such support from Bottorff in cross-examination. Further, Bottorff's testimony to the fact finder is restricted to the **pharmacological effect** in the human body of contaminated and uncontaminated VCDs.

Bottorff is specifically **PRECLUDED** from presenting the following opinions or testimony to a fact-finder:

-Using, defining, explaining the term **"therapeutic equivalence"** or clarifying his interpretation of that term;

-Implying, suggesting, hinting, or opining that **contaminated VCDs bear reduced liability** because they have the same or substantially similar clinical action or pharmacokinetics in the human body because Bottorff is not a qualified expert on the liability of contaminated drugs.

To be clear, although he may opine on the pharmacokinetic action of VCDs in the body, Bottorff is specifically **PRECLUDED** from opining that such action points to or supports reduced legal liability.

**John Flack, MD**

Plaintiffs' motion Doc. No. 2298 is **GRANTED IN PART AND DENIED IN PART.** Defendants asked Flack whether the amounts of NDMA and NDEA found in the contaminated VCDs affected the clinical benefit of those who ingested them. As a medical doctor with much experience in hypertension research and clinical practice, Flack is qualified to opine on this point. Therefore, the Court finds that most of Flack's report is background and of use to the fact-finder because it relates to hypertensive

drugs such as valsartan and their effectiveness in treating high blood pressure and other cardiovascular conditions. Therefore, most of his opinions in Flack's report is **NOT PRECLUDED,** including his opinion that patients received hypertensive benefits from taking contaminated VCDs.

However, two of his opinions are **PRECLUDED**. First, based on his clinical experience, Flack opines that the VCD recalls of 2018 did not adversely affect his ability to treat patients by prescribing comparably effective hypertensive substitutes. This opinion suggests that, if Flack had no trouble regulating the blood pressure of his patients with hypertensive substitutes, then what liability could defendants bear for the VCD contamination? Since patients' health did not suffer and TPPs paid for sufficiently effective, substitute hypertensive medicines they would have had to pay for anyway, where's the harm? Without commenting on the correctness of this opinion, the Court notes Flack's opinion is based solely on anecdotal evidence from his clinical practice. In effect, Flack seeks to generalize from such anecdotal evidence to the universe of all those patients who continued to take contaminated VCDs or who adopted hypertensive substitutes. This opinion is **PRECLUDED** as a "common sense" argument that makes no attempt at anything that resembles reliable methodology.

Second, Flack steps outside his expertise and, without citing reliable methodology, opines that, since patients still had their blood pressure lowered by contaminated VCDs, TPPs also received benefit from the VCDs. Flack implies TPPs gained economic benefit by not having to pay for alternative hypertensives and avoiding payment of serious cardiovascular health outcomes. Flack is indirectly opining not only on defendants' economic loss liability, but also on the economic loss damages owed to TPPs. This opinion is not supported by any literature, research, common medical understanding, economic expertise; it's just Flack's say-so. Therefore, the opinion that TPPs also received economic benefit from the sale of contaminated VCDs is **PRECLUDED.**

More specifically, Flack's opinions are

**NOT PRECLUDED**: on pages 6 - 10;

**PRECLUDED**: on page 11 for those paragraphs that state TPPs benefitted from the VCDs;

**NOT PRECLUDED**: on pages 11 - 14 other than as noted above;

**PRECLUDED**: on page 14 for those paragraphs opining on his anecdotal observations that he saw no drop in clinical benefit with hypertensive substitutes as there's no stated methodology as to whether his observations pertain to a few, some, or all of his hypertensive patients.

**PRECLUDED**: on pages 15 – 16 for those opinions about what TPPs would have done or not done regarding the coverage for prescribed, alternative drugs.

**PRECLUDED**: on pages 16 - 17 for any of his conclusions specifically precluded above.

**Timothy Kosty, BS, MBA**

Plaintiffs' motion Doc. No. 2299 is **GRANTED IN PART AND DENIED IN PART**. Among other things, defendants asked Kosty to explain if TPPs offering prescription drug plans under Medicare Part D (like the TPPs SummaCare and Emblem) are even able to calculate their payments for covered VCDs and by extension their economic losses. In general, Kosty's opinion is that TPPs cannot calculate their economic losses for drugs covered under Medicare Part D because the federal government, as principally responsible for coverage of Medicare-D drugs, have varying and complex payment reimbursements and rebates that resist accurate reconstitution of economic loss.

In addition, Kosty opines that plaintiffs' liability expert Panagos is incorrect in her opinion that TPPs regard the Orange Book as an "assurance" that the generic drug is the same as the RLD. As discussed below, Panagos's liability opinion on how TPPs regard the Orange Book has been precluded as impermissible for lack of reliable methodology as to how TPPs make formulary decisions. And for the same reason, Kosty's opinion about the incorrectness of Panagos' opinion is also **PRECLUDED**. Like Panagos', Kosty's opinion lacks reliable methodology and devolves to just his unsupported assertion.

The heart of Kosty's opinion is that, since he knows how complicated the federal government's rebate and reimbursement system is, it is near impossible for TPPs to calculate actual economic loss. There is no reliable methodology: no assertion of what theses rebates and reimbursement reductions are—not even anecdotal examples, just his asserted understanding of the complexity of the federal government's Medicare Part D rebate system. Kosty's opinions on whether TPPs can calculate economic loss damages from Medicare Part D prescription drug payments are **PRECLUDED**. This is so, not because he is incorrect about the complexity—this Court does not preclude testimony on a credibility determination—but because there is no showing that his testimony is reliably supported.

In addition, and for the same reasons, Kosty's opinions are **PRECLUDED** as to the inability of plaintiffs' expert Laura Craft to calculate TPP economic loss.

Specifically, the opinions in the following paragraphs are **NOT PRECLUDED** in Kosty's liability report: ¶¶49 - 56. There largely provide background on Formulary Management on which he is qualified to opine and which may help the fact-finder. The opinions in the following paragraphs of Kosty's liability report are **PRECLUDED**: ¶¶26, 32, 37, 38, 42 - 48, 62, and 66 - 68.

**Akhilesh Nagaich, PhD**

Plaintiffs' motion Doc. No. 2301 is **GRANTED IN PART AND DENIED IN PART**. Torrent asked Nagaich to opine that Torrent practiced the proper cGMPs both in engaging ZHP as its API supplier and in evaluating ZHP's API. Torrent also asked Nagaich to rebut the opinions in the reports of plaintiffs'

liability experts Laura Plunkett and Philip Russ.

Nagaich states that for the last four years he has worked as an independent Senior FDA / industry consultant, advising pharmaceutical companies on regulatory strategies and clinical development of drugs, vaccines, biologics, etc. In the last 10 years, which corresponds to the relevant period of the negligence claims against Torrent, Nagaich has held six different positions with six different employers. During this relevant period, Nagaich was exploring lateral career moves to learn regulatory management at smaller pharmaceutical companies. The Court does not disqualify Nagaich but raises a question about his overall qualification to opine on the sufficiency of Torrent's cGMP compliance.

More importantly, there is no stated methodology in Nagaich's report. While it is clear that Nagaich reviewed some documents upon which he based his opinion, it's completely unclear whether the reviewed documents were cherry-picked to highlight Torrent's compliance. Without, for example, a transparent statement from Nagaich that he relied on all relevant documents from the FDA, the Court cannot glean how much of his opinions is *ipse dixit* from an expert whose understanding about regulatory compliance may be less than redoubtable.

Section three of Nagaich's report comprising ¶¶20 - 68 discusses background on the drug industry, ANDAs and FDA Inspections, Recommendations, and Letters to a manufacturer. The opinions in these paragraphs are **NOT PRECLUDED** because they are largely background Nagaich is qualified to discuss and may be of help to the fact-finder. Also, **NOT PRECLUDED** for the same reasons are Nagaich's opinions in ¶¶69 -72, ¶¶ 81- 84, ¶¶99 -103, ¶¶ 105 - 106, 108 – 109 of his liability report.

However, the opinions in the following paragraphs of Nagaich's liability report are **PRECLUDED:**

¶¶73 – 78, because Nagaich provides no independent, reliable methodology or reliable metrics supporting his opinion that Ms. Jenny Yang was a qualified auditor of an API manufacturing site. He merely asserts she was qualified. Ordinarily, had Nagaich cited support for Yang's qualifications, the Court would not have precluded these paragraphs but rather viewed them as a credibility clash between Nagaich's opinions and Russ's.

Nonetheless, this is not a credibility problem but an admissibility one. Nagaich properly cannot rebut Russ's opinions that question whether Yang was qualified to audit the ZHP API site because Nagaich has not reliably so shown. If Yang were unqualified, then her observations would be incapable of supporting Nagaich's opinions. Since Nagaich's report is silent as to how Yang is qualified, Yang's reports ring hollow and can support neither Nagaich's opinion that Torrent sufficiently reviewed its API manufacturer not Nagaich's contentions about Russ's opinions.

¶¶ 79 - 80 because Nagaich avers the basic grounding of his opinion is that Torrent followed industry standards. As discussed above, whether industry standards equate to the legal standard for duty of care is a question for the fact-finder. Nagaich is unqualified to opine on what is, in essence, a legal opinion about possible non-negligent behavior.

¶¶ 88 - 94 because, again these opinions are grounded in an assertion that Torrent followed the industry standard, and that such standard sufficed to relieve Torrent of liability. Again, this is a subtle legal opinion Nagaich is unqualified to make;

¶¶ 95 - 97 because the opinion is an unjustified legal interpretation of what constitutes compliance with USP 469;

¶104 for the same reasons as stated for precluding ¶¶79 - 80;

¶ 107 restates opinions precluded above.

**Roger Williams, MD**

Plaintiffs' motion Doc. No. 2301 is **GRANTED IN PART AND DENIED IN PART.** Defendant Teva asked Williams to opine on the sufficiency of Teva's regulatory activity and compliance conduct with respect to finished doses containing contaminated valsartan API. Williams stated three summary opinions:

First: Based on FDA communications, it appeared the FDA did not know or expect the formation of nitrosamines in valsartan API when ZHP changed its solvent extraction process. Therefore, because of the FDA's statements and a corresponding lack of guidance or cGMP information from the FDA, Teva could not have known or expected such formation. Teva therefore acted as a reasonably prudent and careful manufacturer in the making, inspecting and testing of its valsartan products and could not have reasonably foreseen that either the valsartan API or its valsartan finished drug product would contain NDMA and/or NDEA.

Second, since Teva complied with industry standards and all applicable laws, statutes, rules and regulations in obtaining FDA approval for its ANDA products containing valsartan, Teva's contaminated VCD products sold in the US were at all times prior to the recall in July 2018, therapeutically equivalent (both pharmaceutically equivalent and bioequivalent) and AB-rated to their branded counterparts and were not adulterated or misbranded. This is because until FDA identified the contaminated finished doses as adulterated, they were not "adulterated".

Since Teva could not have known about the potential for nitrosamine contamination because the FDA itself did not know, Teva could not and did not make any false or incorrect statements about its valsartan containing products. Moreover, by following the FDA's process for approval of its ANDAs for valsartan-containing finished doses, Teva used reasonable care to ensure its statements about its

valsartan containing products were correct and accurate based on information available at the time.

Third, since generally an FDA Type II DMF review is confidential, and due to the FDA's Type II DMF review of Teva's ANDAs, Teva's conduct was that of a reasonably careful and prudent manufacturer because Teva felt assured that its FDA-approved VCD products were of good, merchantable quality, and therefore suitable for sale in the US market prior to their recall.

Williams re-iterates these opinions in several paragraphs in his report. All three of these opinions and any variations of them in his report are **PRECLUDED** for the following reasons:

Williams' opinions ultimately rely on an "industry standard" rationale. That is, since Teva's conduct either conformed to the industry standards of reviewing API manufacturer reports before recall or relying on the FDA's findings as to whether its API manufacturer's processes sufficed, Teva's review conduct sufficed to show the requisite duty of care in producing and selling its finished doses in the U.S.

These opinions are not helpful to the fact-finder. Although clearly an expert on FDA processes, he is no expert on the legal interpretation of Teva's reliance on "industry standards" to show a requisite duty of care and lack of intent to avoid negligence or fraud liability. This decision has nothing to do with whether Teva is liable or not, but that Williams is not qualified to make such a legal conclusion and wrap it up as *fait accompli* to the fact-finder.

The Court finds that much of Williams' liability report is of use to the fact-finder. Therefore, paragraphs up to and including ¶101 are **NOT PRECLUDED, except for Williams' Summary of Opinions.**

The following opinions in these paragraphs of Williams' liability report are **PRECLUDED:**

¶¶ 20 – 23 as the Summary of Opinions, which deduces a legal conclusion and is therefore not helpful to the fact-finder;

¶107 for Williams' conclusion that nitrosamine formation for the various solvent extraction processes at issue in this MDL was unknown. That FDA chemist reviewers may not have expected nitrosamine formation in no way confirms that such formation was unknown to the chemical expert community. So Williams' conclusion about the unknown nature of nitrosamine formation is based on his belief that the FDA *would have known about it*, which is an untested and unsupported presumption;

¶130 Williams asserts Teva's reasonably prudent conduct is based on what a manufacturer would have "reasonably foreseen", which invokes a legal conclusion about an objective, "reasonably prudent" manufacturer's conduct. Any statements or opinions in his report where Williams uses "reasonably prudent" and "reasonably foreseen" language are **PRECLUDED**, regardless of whether the Court has enumerated the relevant paragraph here;

¶133 Williams subtly overstates the understanding at the time of recall in Jun 2018 about the formation of nitrosamines in the altered solvent extraction processes. He implies that, since the FDA

did not understand or expect nitrosamine formation, there was no understanding in the scientific community about that. This overstatement is supported by neither reliable citation nor methodology;

¶136 Williams states that the contaminated VCDs could not have been "adulterated" before the FDA became aware of the contamination in the summer of 2018. This is sophistry, which attempts to avoid a retrospective characterization of Teva's finished dose products as "adulterated" from the start of the nitrosamine contamination. Again, Williams is stating a legal opinion about whether the FDA applies "adulteration" retrospectively, which is therefore not helpful to the fact-finder;

¶139-140 because these paragraphs are not helpful to the fact-finders' determination of Teva's reasonably prudent conduct;

¶147 as this conclusion is not helpful to the fact-finder;

¶149 because Williams' use of the term "not adulterated" implies that the FDA would apply the term "adulterated" only in a prospective sense. Williams does not consider that the term "adulterated" in a legally appropriate way may characterize the contaminated VCDs before the FDA recall in 2018. He offers no legal justification for his exclusive, prospective use of the term "adulterated" and this presumption is not helpful to the fact-finder;

¶150 the FDA Orange Book is not a warranty, which rebuts the liability report of plaintiffs' expert Panagos. Neither Panagos nor Williams can attest to whether TPPs regard the Orange Book formulation as a warranty or not. None of the parties' liability experts promoting or refuting such a conclusion has backed up their conclusion with reliable evidence from TPPs;

¶157 - 161 Williams implies that FDA ANDA approval correctly, expertly and diligently sufficient gives the ANDA holder a liability pass on the sufficiency of their duty of care in producing drugs equivalent to the RLD. Such ANDA approval creates an "industry standard" that Teva acted with sufficient duty of care. The unstated premise in Williams' opinion is the unswerving correctness of FDA conduct, which lacks evidence and reliable methodology in his report. Moreover, his opinion that an FDA imprimatur of an ANDA is always correct upon which an ANDA seeker may rely as an "industry standard" is a legal conclusion that vitiates the manufacturer's independent liability, which is not helpful to the fact-finder;.

¶162 – 166 mirrors the Summary of Opinions discussed above and for those reasons are **PRECLUDED**.

**Fengtian Xue, PhD**

Plaintiffs' motion Doc. No. 2288 is **GRANTED IN PART AND DENIED IN PART.** Defendant ZHP asked Xue to opine, from an organic chemistry perspective, on whether:

(1) ZHP did sufficient and appropriate risk assessments before making certain changes to its

manufacturing process for the valsartan API;

(2) ZHP did sufficient and appropriate testing of its Valsartan API during the period when the API was sold in the United States;

(3) ZHP knew, or reasonably should have known, that any of the manufacturing processes it used to create Valsartan API could result in the formation of NDMA or NDEA; and

(4) ZHP acted appropriately in responding to reports of NDMA/NDEA in its Valsartan API.

Xue's opinions on these four points are **PRECLUDED** because of his admitted lack of real-world experience and expertise with the organic chemistry of nitrosamine formation in ZHP's manufacturing processes. These include the "Tin", the "TEA" (with or without quenching), and the "Zinc Chloride" processes, all of which form a tetrazole compound in the presence of a catalyst.

This is not to say that Xue does not understand or cannot explain the chemistry of these processes. Nonetheless, the Court finds Xue's opining on the sufficiency of ZHP's conduct during the process changes to be pedantic, not based on his expertise. Xue admits he achieved an understanding of nitrosamine chemistry only after ZHP had asked him to review this chemistry and comment on ZHP's conduct during process changes. Because of Xue's more or less academic approach, the Court cannot discern to what extent Xue's opinions arise from a superficial exercise to provide textbook chemistry explanations and lack a nuanced understanding of the implications of ZHP's moving from the "Tin" process to the "TEA" or "Zinc Chloride" processes. Put simply, the Court is assured Xue has expertise in organic chemistry generally, but not assured as to his expertise in the chemistry of nitrosamine formation and what that means for ZHP's diligence in preventing it in the valsartan API. For this reason, opinions and information from pages 5 to 15 in Xue's liability report are **NOT PRECLUDED** because that may be helpful background to a fact finder.

However, the Court **PRECLUDES** the opinions in the rest and remainder of Xue's report.

## 5.0 PLAINTIFFS' LIABILITY EXPERTS

### Susan Bain, DRSc

Defendants' motion Doc. No. 2284 is **GRANTED IN PART AND DENIED IN PART**. Bain's report does not state why plaintiffs requested it and the Court interprets the report's relevance from its content. Bain reviewed ZHP documents describing ZHP's conduct in changing its solvent extraction process and compares that conduct against certain cGMPs stated in the Code of Federal Regulations ["CFR"]. Besides an absent statement of relevance, Bain's report reveals that she's had a total of 11 years of practice as a reviewer / recommender of regulatory compliance strategies. After achieving a PhD in Regulatory Science in 2011, Bain worked as a quality assurance manager at a small pharmaceutical manufacturer and had a very brief stint at the FDA, where she never worked on or

analyzed 483 letters. To the point, the Court finds Bain qualified, but just barely, to opine on how ZHP's conduct relates to certain cGMPs in terms of sufficient quality assurance.

Bain's opinions on pages 68 to 75 of her report are **PRECLUDED.** Here, Bain opines that the contaminated VCDs were "adulterated", a legal interpretation of the CFR definition, which is only for the fact-finder to reach. In reviewing the Quality Assurance Agreement between ZHP and its U.S. subsidiaries—Prinston, Solco, Huahai U.S.—Bain asserts these subsidiaries did not follow that agreement and hence violated certain cGMPs. This is a legal opinion she is unqualified to make. Bain cites testimony from David Chesney, a defendants' class certification expert, to assert ZHP's executive management teams are largely liable for ZHP's cGMP failures. The Court finds this opinion on ZHP's compliance failure derivative, taken from the liability report of plaintiffs' expert Hecht and defendants' expert Chesney.

Indeed, the Court finds other of Bain's opinions in pages 68 to 75 to be secondarily acquired and backed by little reliable methodology. She has not shown in her report an independent expertise to comment on ZHP's conduct in complying with certain regulations, i.e., cGMPs. Largely based on statements from other experts, Bain's opinions crystallize to this: since the introduction of nitrosamines into valsartan API was improper, ZHP's quality assurance and risk assessment must have been flawed, and therefore ZHP bears liability. Hers is the most basic flaw in logic: working backwards from a result. Bain's specific opinions on pages 68 to 75 of her liability report (and anywhere else they appear in that report) are **PRECLUDED**.

The opinions in the rest and remainder of Bain's liability report are **NOT PRECLUDED** as it is largely background and may be of use to a fact-finder.

**Laura Craft MPH, JD**

Defendants' motion Doc. No. 2287 is **GRANTED IN PART and DENIED IN PART**. Plaintiffs asked Craft to analyze and explain the flow of payments for insurance reimbursement of generic drugs and the electronic record created in that flow. Her methodology includes a review of the following: certain materials produced by the parties, which her previous expert reports in this MDL detail; various contracts dated to between 2011 and 2019 that Emblem Health and SummaCare[2] (assignors for the TPP class representative MSP) had with those Pharmacy Benefit Managers ["PBMs"] which provided services to these assignors; and recall announcements for the VCD products of the defendants in the scheduled, upcoming bellwether trial, viz., ZHP, Teva, and Torrent.

Craft's liability report rehashes earlier opinions in her class certification report, which advocated for the ascertainability of the Economic Loss classes. Here, Craft opines that the legal and

[2] These assignors were Medicare Part D plan sponsors.

technological framework of the U.S. drug supply chain enables the discovery of specific information about drug purchases, not only about consumers but also about their insureds' pay-outs. This relates to liability in an indirect way.

Defendants attack Craft's report as only indirectly fit to the liability task at hand . They also contend that Craft's deposition opinion— that contaminated VCDs had no value— while unexpressed in her report, grounds it. The Court interprets that defendants' opposition is meant to foil this *a priori*, unstated premise. However, the Court does not preclude Craft's report because of an opinion expressed in her deposition testimony. To do so risks an improper reach-through from her deposition because of arguments expressed below (*See infra* for Philip Russ's report) and because Craft's report on its face has acceptable qualifications, relevance, and reliable methodology.

Regarding most of Craft report is background and tangentially relevant to liability, the Court does **NOT PRECLUDE** most of the opinions in Craft's report. For an expert report that is largely background, a court properly restricts the expert from testifying to opinions unstated in the report unless the opposing party expressly examines them at trial.

Therefore, Craft is **PRECLUDED FROM** testifying to a fact finder any other opinions not expressly stated in her liability report but may testify to them if cross-examined on them or if she updates her report to include them.

**Steven Hecht, PhD**

Defendants' motion Doc. No. 2292 sought to preclude the separate reports of two of plaintiffs' experts, Steven Hecht and Ramin Najafi, because both opined on similar subject matter: nitrosamine chemistry and ZHP's liability for the nitrosamine contamination of its API. The Court discusses separately its decision on the admissibility of each expert's report and opinions.

Defendants' motion Doc. No. 2292 to preclude the report of plaintiffs' expert Steven Hecht is **DENIED.** Plaintiffs asked Hecht to discuss, from an organic chemistry perspective, the root cause of the nitrosamine contamination in ZHP VCDs and to opine on the relative facility of avoiding such contamination. Because of his years-long experience working in nitrosamine chemistry, Hecht is qualified to opine on nitrosamine formation / detection. The subject matter of his report is squarely relevant to liability. Hecht's methodology was to review both ZHP documents and FDA documents related to the contamination. Hecht's opinions includes:

-the contamination of the solvent dimethyl formamide with dimethylamine or the formation of dimethylamine because of the quenching of azide with nitrous acid, formed from nitrite under acidic conditions, was foreseeable, which ZHP should have evaluated;

-the addition of the nitrite to quench the azide was the critical step to the contamination;

- ZHP disregarded the potential for nitrosamine formation when undertaking this step; and

- ZHP should have been looking for nitrosamine formation based on the change in its quenching steps; and

-ZHP should have expected the production of NDMA in its Zinc Chloride process because it has long been known that dimethyl formamide can degrade into diemethylamine, which can then form NDMA.

Defendants assert Hecht's methodology is not reliable. He cited no scientific literature that informs that a reaction between the TEA and sodium nitrite during quenching is likely to create nitrosated amines, such as NDMA. Further, Hecht cited only one Australian textbook that even discussed nitrosamine formation but under different formation conditions (closer to the boiling point) than ZHP used. Therefore, defendants argue ZHP had no reasonable expectation that the TEA process with quenching would result in nitrosamine contamination.

Plaintiffs counter that Hecht reviewed ZHP's own deviation investigation reports in which ZHP's testing showed that both NDMA and NDEA could form under its process conditions of quenching TEA with sodium nitrite. Hecht also reviewed FDA documents, such as a 2018 Warning Letter, informing ZHP that it had not considered the potential for mutagenic impurity formation when changing the solvent to dimethyl formamide. Therefore, Hecht's opinions can only be considered reliable as they are grounded not only in his experience of nitrosamine formation but also by his reading (not his interpretation) of ZHP's own testing reports and FDA communications.

In essence, the defendants' and the plaintiffs' arguments go to the weight of Hecht's liability conclusions and no doubt may preview a cross-examination of Hecht. Specifically, defendants' arguments regarding the reliability of Hecht's method—the paucity or sufficiency of the scientific literature about nitrosamine formation— do not negate the reliability of his literature review or the admissibility of his opinions based on that review, but goes to the weight of Hecht's opinions.

**Ramin Najafi, PhD**

Defendants' motion Doc. No. 2292 as regards the report of plaintiffs' expert Ramin Najafi is **GRANTED IN PART and DENIED IN PART.**

Najafi's report mirrors Hecht's in that it discusses ZHP's liability for not considering more carefully and with foresight the chemical implications of changing their solvent extraction processes. His report is fit for the purpose. The Court finds Najafi qualified to opine because of his 35-year long organic chemistry experience as well as his 12-plus years of experience in helping drug companies develop new products by following stringently the regulatory guidance from the FDA, ICH, USP, etc. Najafi's opinions are based on his chemistry experience, his regulatory compliance, and his review of FDA and ZHP documentation.

Because of the similarity in fit and reliable methodology between Najafi's and Hecht's reports, the Court finds most opinions in Najafi's report not precluded. Specifically, Najafi is **NOT PRECLUDED** from using the term "adulterated" so long as he closely limits that use to the language set forth in the Food, Drug, and Cosmetic Act, 21 U.S. 351(a)(2)(B).

Ultimately, plaintiffs put forth three reports from liability experts opining on ZHP's conduct relating to nitrosamine chemistry and ZHP's duty of care to analyze the chemical implications of the changes to its solvent extraction process. In general, the Court notes these distinctions among the three reports: Hecht opines on whether ZHP's chemical expertise sufficed to recognize that the changes in their chemical processes could result in nitrosamine formation. Russ opines on whether Ds should have considered the ramifications of making those changes. And, Najafi's report directly contradicts defendants' organic chemistry expert, Xue.

More specifically, Najafi's task is to explain the **chemistry** of nitrosamine formation and why nitrosamines are carcinogenic in nature because of their chemical structures. As it may be quite easy to drift into biological explanations why nitrosamines may cause cancer, the Court issues a general restriction that Najafi's opinions that waft into biological explanations of such effects are **PRECLUDED.** In particular, Najafi's opinions that contaminated VCDs provided zero benefit to consumers or their TPPs are **PRECLUDED**. Najafi is no economic or medical expert qualified to opine on the benefit of contaminated VCDs to patients.

Nonetheless, his chemical explanations of nitrosamine effects are **NOT PRECLUDED**. Also, **NOT PRECLUDED** is Najafi's opinion regarding the quality of ZHP's risk assessment analysis. He opined that, had ZHP done the research and conducted a thorough risk analysis when changing the solvent extraction process, ZHP would have been able to at least guess about possible nitrosamine formation based on known, general properties of the chemicals involved and their reactivity.

As with Hecht's report, defendants opposed Najafi's because he cites little contemporaneous literature that would have prompted ZHP to ask about possible nitrosamine formation in its changed solvent extraction process. Inasmuch as Hecht's and Najafi's methodologies are similar and reliably based on ZHP's own documentation and the FDA's published insight, both reports reliably raise questions about ZHP's diligence in exploring the possible chemical effects in its changed processes. As with Hecht's report, the Court finds defendants' opposition relates not to the admissibility of Najafi's opinions but to their weight.

**Kaliope Panagos, PharmD, R.Ph.**

Defendants' motion Doc. No. 2291 is **GRANTED IN PART AND DENIED IN PART.** Plaintiffs asked Panagos to opine on the type of information that TPPs rely on and consider when selecting

generic drugs for inclusion in their formularies. Such opinion relates indirectly to whether TPPs have incurred economic loss for their full or partial payments of VCDs. Panagos' liability report is similar to her class certification one. And as previously, the Court precludes many of her opinions for the same reasons expressed in the class certification opinion.

In general, Panagos' interpretation that an FDA approval of an ANDA drug translates into an "assurance" to TPPs of that drug's therapeutic- and bio- equivalence to the RLD is **PRECLUDED.** Specifically, the information and opinions expressed in the following paragraphs of her report are **PRECLUDED** from reaching the fact-finder: ¶¶ 80, 82 - 84, 87 - 88, 90, 92 – 92, 97 – 98, and 102 – 105. Also **PRECLUDED** are the opinions in Panagos' Summary sections IX – X, XII, and XIV.

Although the rest and remainder of the opinions in Panagos' report are **NOT PRECLUDED**, Panagos is **PRECLUDED in any testimony to a fact-finder** from using the terms "therapeutic equivalence" and "bio-equivalence" or equating these terms to each other. Such conclusions are not helpful to the fact-finder.

**Laura Plunkett, PhD**

Defendants' motion Doc. No. 2285 is **GRANTED IN PART AND DENIED IN PART**. Plaintiffs asked Plunkett to opine, from a toxicology perspective, on the human health risks from ingesting contaminated VCDs over an extended duration. Her particular expertise as a toxicologist and pharmacologist in academia and in research for over 30 years as well as her work as a regulatory consultant conducting risk/benefit analyses of human drugs qualifies her in this task. She is especially familiar with valsartan and cancer risk assessment of genotoxic compounds. Plunkett's methodology was to analyze defendants' documents in light of human health risk assessment principles used by drug regulators in assessing drug safety. She also applied to the reviewed documents a weight of the evidence method gleaned from a body of research and literature and referred to a tome that explains how experts use this method.

Plunkett opines that defendants' VCDs—both API and finished dose products—are adulterated because of the inclusion of nitrosamines. Plunkett's opinion on whether valsartan API contaminated with nitrosamine constitutes an "adulterated" drug is allowed because she is qualified to opine on the purity or impurity of a drug from a toxicology point of view. Simply, her ability to opine on the meaning of adulteration arises from her expertise. For that reason, her opinions in ¶62 of her report is **NOT PRECLUDED**.

However, in subtle ways, some of Plunkett's statements and opinions cross the line into legal guidance for those areas where her opinions do not arise from her toxicology expertise. Because of this subtlety, the Court has reviewed Plunkett's report closely to identify precluded and non-precluded

paragraphs. Besides ¶62, the following paragraphs in Plunkett's report are **NOT PRECLUDED**, but testimony to a fact finder may be restricted according to the Court's instructions below:

¶¶ 15-20 as background;

¶21 only to allow her to quote the FDA definition of "pharmaceutical equivalence";

¶22 only to allow her to quote 21 U.S.C. 355 as to the definition of the term "bioequivalence";

¶¶23 – 25 as background;

¶26 only to the extent that her cited section of USP was the one in play BEFORE THE FDA RECALL OF VCDs in July 2018;

¶¶27 – 28 only to the extent that Plunket must QUOTE the FDA's own language in the EIR sent to ZHP as to why ZHP's risk assessments were inadequate;

¶29, 51, 54;

¶30 only to the extent Plunkett QUOTES ZHP's Dr. Min Li testimony;

¶32 only to the extent Plunkett QUOTES from the FDA warning letter to ZHP of 29 Nov 2018 in which the FDA disagrees with ZHP that its risk assessment was adequate because it was in line with "current industry practice";

¶36 only as to her reading 21 CFR 314.98;

¶37 - 43 as background;

¶55 only if Plunkett quotes from letters sent by Torrent and Teva to ZHP to inform ZHP of their recalls;

¶56 as background only to the extent that the GAO document she cites from was AFTER THE FDA RECALL OF VCDs in July 2018;

¶57 as background.

The following opinions in Plunkett's report are **PRECLUDED**:

¶21 she may not testify to her interpretation that "therapeutic equivalence" equates to "pharmaceutical equivalence", which is not helpful to the fact-finder;

¶26 **IF** her citation to the USP was to a version issued AFTER THE FDA RECALL OF VCDs in July 2018;

¶27 she may not offer hers or any other opinion as to the inadequacy of ZHP risk assessments on the changes in ZHP's solvent extraction process. She may only quote the FDA's statements.

¶31 and ¶34 she may not cite to a treatise or reference on risk assessments, which is dated AFTER THE FDA RECALL OF VCDs in July 2018;

¶32 as irrelevant regarding proposed changes to the USP that would may or have gone into effect AFTER THE FDA RECALL OF VCDs in July 2018;

¶33 as irrelevant or unfit for the purpose of the report;

¶35 because she may not offer a legal assumption she is unqualified as a toxicologist to make;

¶36 her opinions whether the FDA will find a label misleading requires legal expertise for which she is unqualified;

¶44- 50 her opinions repeat opinions of other plaintiffs experts', are derivative, and should be presented directly by the relevant experts to the fact finder;

¶52 as pure *ipse dixit*, lacking reliable methodology for not stating with reliable specificity what are "necessary" risk assessments ZHP should have taken;

¶53 as a legal opinion unsupported by citation;

¶55 she cannot testify to her interpretation about communications between ZHP and Torrent and Teva, but only may quote from those communications;

¶58 as outside Plunkett's expertise and experience;

¶¶59 - 63 Plunkett's interpretation of the FDA's 2018 Warning Letter to ZHP is a legal opinion that is not helpful to the fact-finder.

**Philip Russ, BS**

Defendants' motion Doc. No. 2296 is **DENIED**. Plaintiffs asked Russ to opine on the quality of Teva's and Torrent's compliance with cGMPs in making their finished dose products. Plaintiffs also asked him to explain how Teva's and Torrent's corporate compliance behavior contributed to their failure to discover nitrosamines in the valsartan API they bought. Russ's specific qualifications are his work as consultant to pharmaceutical management for nearly 30 years in cGMP compliance. His methodology was to review Teva's and Torrent's documents in light of those industry standards which he would have used in his everyday consulting practice as well as FDA regulations and cGMP guidances. More specifically, Russ was looking at the adequacy of these firms' corporate structure, and in particular, their quality and management corporate practices, in order to gauge the sufficiency of the monitoring and oversight methods.

Russ's general opinion is that both Teva's and Torrent's quality and management systems prompted firm-wide, inadequate monitoring and oversight of their API suppliers. Such overarching failure resulted in conduct at several corporate levels that deviated from quality cGMPs and from industry standards.

Defendants oppose Russ's opinion because of his *ab initio* premise: since the finished dose manufacturers did not perform their own testing of ZHP's API, then *ipso facto* Teva and Torrent failed their quality and monitoring duty of care. Further, defendants oppose Russ's interpretations of the motive, intent and state of mind of the finished dose manufacturers in choosing to use ZHP's valsartan API.

The Court has not precluded Russ's report because he has applied a reliable methodology. His opinions on the inadequacy of Teva's and Torrent's quality and monitoring standards and their motives for not independently testing ZHP's API come directly from his review of defendants' own documents. Such review is a reliable methodology because Russ's opinions stem from defendants statements and conduct. Even if Russ approached the task with an *a priori* presumption, Russ' years-long experience as a consultant to pharmaceutical management, gives him the requisite expertise to glean from Teva's and Torrent's documents the reasons why Teva and Torrent created their quality / monitoring programs and corporate structure. Russ's methodology—his review of the reality of Teva's and Torrent's own statements and conduct—has the potential to alter any *a prior* presumption, which is why Russ's opinions are not precluded.[3]

Defendants' arguments go to the correctness of Russ's opinions, not to his qualifications to opine or the fitness and reliability of his opinions. Courts do not engage in weighing the correctness of an expert's opinion, rather the reliability of them.[4]

Defendants also seek to preclude Russ's deposition opinions that were not properly disclosed in his expert report. However, the Court does not preclude those opinions because there exist several checks to presenting such new, unqualified testimony in the Federal Rules. First, although *Federal Rule of Evidence 705*[5] would not limit Russ's "new" deposition testimony from being presented at trial to a fact-finder, the defendants can require Russ to reveal the bases of his "new" opinions in cross-examination and therefore expose them as unreliable, irrelevant, or unqualified.[6] Further, to the extent that Russ's new deposition testimony is to be presented to the fact-finder, *Fed. R. Civ. Proc.*

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[3] *See Aetna Inc. v. Express Scripts, Inc.*, 261 F.R.D. 72 (E.D. Pa 2009).

"Even assuming that [the expert's] analysis was flawed, in part, due to his misapplication of free or discounted pricing, 'flaws' in an expert's investigative process do not render the opinion excludable. An expert's opinion is suspect when it is based on a 'subjective belief' or 'unsupported speculation' but remains admissible so long as the process used by the expert is reliable. [*In re*] *Paoli [R.R. Yard PCB Litigation]*, 35 F.3d [717] at 744–45 [3d Cir. 1994]."

*Id*. at 81.

[4] *See*, *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Litigation*, 509 F.Supp.3d 116 (D.N.J. 2020).

> Careless and shoddy recordkeeping of tests of various cell lines by the expert "do not indicate, however, that the actual data collected from the cell lines were unreliable or somehow altered in bad faith. As such, these issues go to the weight of [the expert's] opinion and the credibility of his testimony. *Crowley v. Chait*, 322 F. Supp. 2d 530, 540 (D.N.J. 2004) ('*Daubert* does not require that an expert's testimony be excluded simply because he admitted ... his own mistakes or retracted his false statements.'); *see also Oddi*, 234 F.3d [136] at 145-46 [3d Cir. 2000] (the test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct)".

*Id*. at 146.

[5] *FRE 705*. Disclosing the Facts or Data Underlying an Expert

Unless the court orders otherwise, an expert may state an opinion — and give the reasons for it — without first testifying to the underlying facts or data. But the expert may be required to disclose those facts or data on cross-examination.

[6] *See, e.g., Carnegie Mellon University v. Marvell Technology Group, LTD. et al.*, Civil Action No. 09-290, 2012 WL 12894850 (W.D .Pa. 18 Dec 2012) [*exemplifying* the opposing party's right at trial to object to the discrepancies among the expert witnesses' report, deposition testimony, and trial testimony].

*26(e)(2)*[7] requires that Russ's report be supplemented with his new deposition testimony. If his report is not so supplemented, then defendants may object at trial.

## 6.0 CONCLUSION

The Court's decisions regarding the motions to preclude expert liability reports listed in Table 1 and 2 *supra* are set forth in an accompanying Order of this date.

Dated: 5 January 2024

/s Robert B. Kugler
The Honorable Robert B. Kugler
United States District Judge

[7] *Fed. R. Civ P. 26 (e)(2)* Supplementing Disclosures and Responses.

. . .

(2) *Expert Witness.* For an expert whose report must be disclosed under *Rule 26(a)(2)(B)*, the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition. Any additions or changes to this information must be disclosed by the time the party's pretrial disclosures under *Rule 26(a)(3)* are due.